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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,467	03/27/2002	Howard D. Dean	28728-65	9628

21130 7590 02/26/2010

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EXAMINER	
LAURITZEN, AMANDA L	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
02/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@beneschlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/089,467	DEAN ET AL.	
	Examiner	Art Unit	
	Amanda L. Lauritzen	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to communications filed 08 September 2009. Amendments to the claims are not interpreted to introduce new matter.

Response to Arguments

Applicant's arguments have been fully considered and they are persuasive but are moot in view of new grounds of rejection presented in view of Bradbury et al. (US 2002/0059049).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-7 and 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0059049).

Bradbury et al. disclose a system and corresponding method for determining a shape of an implant prior to surgical implantation into a subject, the method including producing an image of a volume of the defective hard tissue (as in [0016]-[0017], in which CT tomographic images constitute a volume, [0044], in which the surgical reconstruction site is imaged, which is understood to inherently include both defective and non-defective regions of hard tissue—the defective regions to be reinforced by the implant and the non-defective regions necessary for securing the implant). A template is produced in CAD, and it is disclosed that it can comprise a surface or wire-frame representation, as in [0047]. The template (digital model) is deformable in the sense that it may be "modified to add attachment structure, fixture points, separation markings," as in [0048]. A three-dimensional volume model 502 is disclosed and shown in Fig. 6. It is disclosed that the edges of bone and discerning various boundaries from the radiological data, as in [0105], such that curves can be fit to define these surfaces. While it is not expressly disclosed that ridge curves and tilling curves are included in the template, the depiction of the three-dimensional model in Fig. 6 shows there to be distinct ridges along the surface of the template so as to match the anatomical surface topography. Additionally, the template is disclosed to feature curved surfaces, as in [0056].

The external shape of the implant is determined as a function of the template, as modified to fit the topography of the surgical reconstruction site. The implant is understood to be appropriately sized to fit within the contours of the defective portion of hard tissue and to attach at non-defective tissue (e.g., for implants that attach to existing bone, as in [0056], also [0060]).

Regarding claims 4-6, geometric fitting of the template is disclosed at [0056], which is to include discerning the area of defective tissue that the implant is being designed to replace. Curve and surface fitting are also disclosed, which are understood as forms of warping the template to match the anatomical topography.

Regarding claim 7, "normative" shapes are determined from a library or database, for example, a database of demographic bone density information, as in [0048]. The normative shape is also determined such that the shape of the implant is designed to match that of the normally functioning joint.

Regarding claim 10, segmenting of hard tissue within the image is disclosed at [0056], also boundary definition at [0105]. Segmenting layers is additionally disclosed at [0132].

Regarding claim 18, a CAD model is optionally based on an average of two scans, as in [0059], in which case the fitting and warping techniques on the template discussed above would be based on an average shape. The disclosed wire-frame model is understood to include geodesic lines or equivalents along the curved surfaces of the model, as in [0047].

3. Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al., as applied to claims 7 and 18 above, further in view of Ateshian et al. (US 6,126,690).

Bradbury et al. teach all features of the invention as substantially claimed, as detailed above, but do not specifically detail determining a shape of an implant from healthy hard tissue that mirrors the hard tissue surface of interest; however, in the same field of endeavor, Ateshian et al. disclose imaging the complementary healthy joint to ascertain a mirror image of the surgical site in its healthy and functional state (col. 1, lines 24-31; lines 36-45; line 47-54; col. 2,

lines 3-13; lines 44-47; 61-67; col. 3, lines 1-54; col. 7, lines 33-52; col. 11, lines 24-39). It would have been obvious to one ordinarily skilled in the art at the time of invention to include determining the shape of an implant based on a mirror image healthy joint, as taught by Ateshian et al., in the method of Bradbury et al., in order to model the implant based on a healthy and functional state.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amanda L. Lauritzen/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737